



# UNITED STATES PATENT AND TRADEMARK OFFICE

40  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,149	01/19/2001	Eberhard Nieschlag	PLOVIN-3A	8178

23599 7590 07/13/2005

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
2200 CLARENDON BLVD.  
SUITE 1400  
ARLINGTON, VA 22201

EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
----------	--------------

1618

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/764,149

Applicant(s)

NIESCHLAG ET AL.

Examiner

Simon J. Oh

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 130-138, 143-154, 158-170, 172, 173 and 175-187 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 130-138, 143-154, 158-170, 172, 173 and 175-187 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Papers Received*

Receipt is acknowledged of the applicant's amendment, response, and petition for extension of time, all received on 05 February 2004.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 139-142, 155-157, 171, and 174 over Guerin *et al.* is rendered moot with the cancellation of those claims.

The rejection of Claims 130-138, 143-154, 158-170, 172, 173, and 175-185 over Guerin *et al.* is maintained.

Claims 186 and 187 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guerin *et al.*

Guerin *et al.* discloses the combination of progestagens and androgens and its use for male contraception (See abstract and entire article). The reference teaches progestagens such as medroxyprogesterone acetate and norethisterone and androgens such as testosterone and testosterone undecanoate (See Page 188, Lines 14-22). The reference also teaches that both steroid classes can be administered by intramuscular injections; that azoospermia or oligospermia are obtained (See Page 188, Lines 4-8), and the use of various amounts of each active agent.

The instant claims differ from the reference by reciting various dosages of the active ingredients. However, the preparation of various pharmaceutical formulations having various

Art Unit: 1618

amounts of the active agents is within the purview of one having ordinary skill in the art at the time that the instantly claimed invention was made. It is also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality or of unexpected results. See *In re Russell*, 439, F.2d 1228, 169 USPQ 426 (CCPA 1971).

### ***Response to Arguments***

Applicant's arguments filed 05 February 2004 have been fully considered but they are not persuasive.

Although the applicant has raised the issue of the validity of the *Guerin et al.* reference, it is the position of the examiner that this is not sufficient to overcome the prior art rejection of record. In the view of the examiner, as a matter of interpreting the disclosure of the prior art, there is no definitive indication that the specific disclosure of intramuscular injection was intended by the authors of the reference to be directly attributed to the cited references, as opposed to the disclosure of the use of the combination of progestagens and androgens for the purpose of male contraception. Therefore, the examiner will maintain the prior art rejection of record.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the

Art Unit: 1618

THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1618

sjoh

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600